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JAN - 5 1999

Ronald A. Daignault
Merchant Gould Smith Edell Welter & Schmidt
3100 Norwest Center
90 South Seventh St.
Minneapolis MN 55402-4131

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,938,763

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,938,763, which claims the product ATRIDOX™, is ineligible for patent term extension under 35 U.S.C. § 156.

An application for extension of the patent term of U.S. Patent No. 4,938,763 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on October 23, 1998. The application was filed by Atrix Laboratories, the patent owner of record. Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a human drug product known by the tradename ATRIDOX™ having the active ingredient doxycycline hyclate. ATRIDOX™ was approved for commercial use and sale by the Food and Drug Administration (FDA) on September 3, 1998.

A determination has been made that U.S. Patent No. 4,938,763 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of ATRIDOX™.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The application for patent term extension states that the product ATRIGEL® Delivery System contains two active ingredients: doxycycline hyclate and polymeric formulation delivery system, both of which have been previously approved for commercial use or sale by the Food and Drug Administration. A review of the Prescription Drug Product List, of the text "Approved Drug Products with Therapeutic Equivalence Evaluations" (FDA's Orange Book), 18th Edition, 1998, page 3-125 and 3-125 (copy attached), reveals that many products containing the active ingredient doxycycline hyclate have been previously approved. For example, in oral capsule form, the products DOXY-LEMMON (50 mg) was approved on August 23, 1984, and DOXYCYCLINE HYCLATE (100 mg, Barr) was approved on January 28, 1983. Furthermore, doxycycline hyclate has also been approved in an injectable form with the products

DOXYCYCLINE (100 mg base/vial) on March 9, 1998. See also USPDI, Volume I, Drug Information for the Health Care Professional, Doxycycline Hyclate, pages 2828- 2829.

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 4,938,763 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredient in the approved product is doxycycline hyclate. The polymeric formulation delivery system included in syringe B of ATRIDOX™ is not an active ingredient since doxycycline hyclate, not the polymeric formulation system, provides the desired pharmacological activity for treatment of chronic adult periodontitis.[1] The prior approval under Section 510(k) of the Federal Food, Drug and Cosmetic Act of poly(DL-lactide) and N-methyl-2-pyrrolidone, ingredients of the polymeric formulation system, confirms that FDA does not consider these ingredients to be drugs and instead considers the polymeric formulation to be a medical device. As noted in the application for patent term extension and as shown in the Prescription Drug Product List of the Approved

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[1]The term "active ingredient" is defined in 21 CFR 60.3(b)(2) as "(2) any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or of animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect."

Drug Products with Therapeutic Equivalence Evaluations, for example), the active ingredient doxycycline hyclate had been approved for commercial marketing and use prior to the approval of the applicant's product. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), applicant's approval of doxycycline hyclate does not qualify as the first permitted marketing or use of the active ingredient. Since the approval of ATRIDOX™ was not the first permitted marketing or use of the active ingredient thereof, the patent is not eligible for patent term extension based upon the regulatory review of ATRIDOX™. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

In view of the above, the term of U.S. Patent No. 4,938,763 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product ATRIDOX™ and the application for patent term extension, filed October 23, 1998, is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Assistant Commissioner for Patents Box Patent Ext. Washington, D.C. 20231
By FAX:	(703) 308-6916 Attn: Special Program Law Office
By hand:	One Crystal Park, Suite 520 2011 Crystal Drive Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

Attachments

DOXYCYCLINE

Summary of Differences

Indications: Also indicated for the prevention of malaria.

Precautions:

Drug interactions and/or related problems—
Also interacts with barbiturates, carbamazepine, and phenytoin.
No interaction with methoxyflurane.

Laboratory value alterations—No increase in BUN concentrations.

Medical considerations/contraindications—Caution not needed in renal impairment.

General dosing information:

No dosage reduction in renal impairment.

May be taken with food, milk, or carbonated beverages.

Additional Dosing Information

Even though approximately 40% of a dose of doxycycline may be eliminated through the kidneys in patients with normal renal function, patients with impaired renal function do not generally require a reduction in dose since doxycycline alternatively may be eliminated through the liver, biliary tract, and gastrointestinal tract and does not have the antianabolic effect of other tetracyclines.

For oral dosage forms only:

- Doxycycline may be taken with food or milk if gastrointestinal irritation occurs.

Oral Dosage Forms

Note: Bracketed uses in the *Dosage Forms* section refer to categories of use and/or indications that are not included in U.S. product labeling.

DOXYCYCLINE FOR ORAL SUSPENSION USP

Usual adult and adolescent dose: Antibacterial (systemic); antiprotozoal—Oral, 100 mg (base) every twelve hours the first day, then 100 to 200 mg once a day; or 50 to 100 mg every twelve hours.

Note: Gonococcal infections, uncomplicated (except anorectal infections in men)—Oral, 100 mg (base) every twelve hours for seven days; or 300 mg initially, then 300 mg one hour later.

Malaria prophylaxis—Oral, 100 mg (base) once a day. Prophylaxis should begin one or two days before travel to the malarious area, be continued daily during travel, and for four weeks after the traveler leaves the malarious area.

Nongonococcal urethritis caused by *Chlamydia trachomatis* or *Ureaplasma urealyticum*, and
Uncomplicated urethral, endocervical, or rectal infection caused by *Chlamydia trachomatis*—Oral, 100 mg (base) two times a day for at least seven days.

Syphilis (primary and secondary)—Oral, 150 mg (base) every twelve hours for at least ten days.

[Traveler's diarrhea (prophylaxis)]—Oral, 100 mg (base) once a day for three weeks.

Usual adult prescribing limits: Up to 300 mg (base) daily; or up to 600 mg daily for five days in acute gonococcal infections.

Usual pediatric dose: Antibacterial (systemic); antiprotozoal—
Children 45 kg of body weight and under: Oral, 2.2 mg (base) per kg of body weight every twelve hours the first day, then 2.2 to 4.4 mg per kg of body weight once a day; or 1.1 to 2.2 mg per kg of body weight every twelve hours.
Children over 45 kg of body weight: See *Usual adult and adolescent dose.*

Note: Malaria prophylaxis—Children over 8 years of age: Oral, 2 mg per kg of body weight, up to 100 mg, once a day. Prophylaxis should begin one or two days before travel to the malarious area, be continued daily during travel, and for four weeks after the traveler leaves the malarious area.

Infants and children up to 8 years of age—All tetracyclines form a stable calcium complex in any bone-forming tissue. Accordingly, tetracyclines may cause permanent yellow-gray-brown discoloration of the teeth, as well as enamel hypoplasia. Also, a decrease in linear skeletal growth rate may occur in premature infants. Therefore, tetracyclines are not recommended in these age groups unless other drugs are unlikely to be effective or are contraindicated.

Strength(s) usually available:
U.S.—
25 mg per 5 mL, when reconstituted according to manufacturer's instructions (base) (Rx) [*Vibramycin*].
Canada—
Not commercially available.

Packaging and storage: Prior to reconstitution, store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container.

Stability: After reconstitution, suspensions retain their potency for 14 days at room temperature.

Auxiliary labeling:
- Shake well.
- Continue medicine for full time of treatment.
- Do not take within 1 to 3 hours of other medicines.
- Avoid too much sun or use of sunlamp.
- Beyond-use date.

Note: When dispensing, include a calibrated liquid-measuring device.

DOXYCYCLINE CALCIUM ORAL SUSPENSION USP

Usual adult and adolescent dose: See *Doxycycline for Oral Suspension USP.*

Usual adult prescribing limits: See *Doxycycline for Oral Suspension USP.*

Usual pediatric dose: See *Doxycycline for Oral Suspension USP.*

Strength(s) usually available:
U.S.—
50 mg per 5 mL (base) (Rx) [*Vibramycin*].
Canada—
Not commercially available.

Packaging and storage: Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container. Protect from freezing.

Auxiliary labeling:
- Shake well.
- Continue medicine for full time of treatment.
- Do not take within 1 to 3 hours of other medicines.
- Avoid too much sun or use of sunlamp.

Note: When dispensing, include a calibrated liquid-measuring device.

DOXYCYCLINE HYCLATE CAPSULES USP

Usual adult and adolescent dose: See *Doxycycline for Oral Suspension USP.*

Usual adult prescribing limits: See *Doxycycline for Oral Suspension USP.*

Usual pediatric dose: See *Doxycycline for Oral Suspension USP.*

Strength(s) usually available:
U.S.—
50 mg (base) (Rx) [*Monodox; Vibramycin;* GENERIC].
100 mg (base) (Rx) [*Doxy-Caps; Monodox; Vibramycin;* GENERIC].
Canada—
100 mg (base) (Rx) [*Apo-Doxy; Doxycin; Novodoxylin; Vibramycin*].

Packaging and storage: Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container.

Auxiliary labeling:
- Continue medicine for full time of treatment.
- Do not take within 1 to 3 hours of other medicines.
- Avoid too much sun or use of sunlamp.
- Keep container tightly closed in a dry place.

DOXYCYCLINE HYCLATE DELAYED-RELEASE CAPSULES USP

Usual adult and adolescent dose: See *Doxycycline for Oral Suspension USP.*

Usual adult prescribing limits: See *Doxycycline for Oral Suspension USP.*

Usual pediatric dose: See *Doxycycline for Oral Suspension USP.*

Strength(s) usually available:

U.S.—

100 mg (base) (Rx) [*Doryx;* GENERIC].

Canada—

100 mg (base) (Rx) [*Doryx*].

Packaging and storage: Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container.

Auxiliary labeling:

- Continue medicine for full time of treatment.
- Do not take within 1 to 3 hours of other medicines.
- Avoid too much sun or use of sunlamp.
- Keep container tightly closed in a dry place.
- Swallow capsules whole.

Note: Doxycycline Delayed-release Capsules USP contain enteric-coated pellets.

DOXYCYCLINE HYCLATE TABLETS USP

Usual adult and adolescent dose: See *Doxycycline for Oral Suspension USP.*

Usual adult prescribing limits: See *Doxycycline for Oral Suspension USP.*

Usual pediatric dose: See *Doxycycline for Oral Suspension USP.*

Strength(s) usually available:

U.S.—

100 mg (base) (Rx) [*Doxi Film; Vibra-Tabs;* GENERIC].

Canada—

100 mg (base) (Rx) [*Doxycin; Vibra-Tabs*].

Packaging and storage: Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container.

Auxiliary labeling:

- Continue medicine for full time of treatment.
- Do not take within 1 to 3 hours of other medicines.
- Avoid too much sun or use of sunlamp.
- Keep container tightly closed in a dry place.

Parenteral Dosage Forms

DOXYCYCLINE HYCLATE FOR INJECTION USP

Usual adult and adolescent dose: Antibacterial (systemic); antiprotozoal—Intravenous infusion, 200 mg (base) once a day or 100 mg every twelve hours the first day, then 100 to 200 mg once a day; or 50 to 100 mg every twelve hours.

Note: Syphilis (primary and secondary)—Intravenous infusion, 150 mg (base) every twelve hours for at least ten days.

Usual adult prescribing limits: Up to 300 mg (base) daily.

Usual pediatric dose: Antibacterial (systemic); antiprotozoal—Children 45 kg of body weight and under: Intravenous infusion, 4.4 mg (base) per kg of body weight once a day or 2.2 mg per kg of body weight every twelve hours the first day; then 2.2 to 4.4 mg per kg of body weight once a day or 1.1 to 2.2 mg per kg of body weight every twelve hours.

Children over 45 kg of body weight: See *Usual adult and adolescent dose.*

Note: Infants and children up to 8 years of age—All tetracyclines form a stable calcium complex in any bone-forming tissue. Accordingly, tetracyclines may cause permanent yellow-gray-brown discoloration of the teeth, as well as enamel hypoplasia. Also, a decrease in linear skeletal growth rate may occur in premature infants. Therefore, tetracyclines are not recommended in these age groups unless other drugs are unlikely to be effective or are contraindicated.

Size(s) usually available:

U.S.—

100 mg (base) (Rx) [*Doxy; Vibramycin;* GENERIC].

200 mg (base) (Rx) [*Doxy; Vibramycin;* GENERIC].

Canada—

100 mg (base) (Rx) [*Vibramycin*].

Packaging and storage: Prior to reconstitution, store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Protect from light.

Preparation of dosage form: To prepare initial dilution for intravenous use, add 10 mL of sterile water for injection or other suitable diluents (see manufacturer's package insert) to each 100-mg vial or 20 mL of diluent to each 200-mg vial. The resulting solution containing the equivalent of 100 to 200 mg of doxycycline may be further diluted in 100 to 1000 mL or in 200 to 2000 mL of suitable diluent, respectively.

Stability:

After reconstitution, intravenous infusions of doxycycline hyclate retain their potency for 12 hours at room temperature or for 72 hours if refrigerated at concentrations of 100 mcg (0.1 mg) to 1 mg per mL in suitable fluids (see manufacturer's package insert). Intravenous infusions of doxycycline hyclate retain their potency for 6 hours at room temperature at concentrations of 100 mcg (0.1 mg) to 1 mg per mL in lactated Ringer's injection or 5% dextrose and lactated Ringer's injection. Infusions must be protected from direct sunlight during administration.

If frozen immediately after reconstitution with sterile water for injection, solutions at concentrations of 10 mg per mL retain their potency up to 8 weeks at −20 °C (−4 °F). Once thawed, solutions should not be refrozen.

Additional information:

Concentrations less than 100 mcg (0.1 mg) per mL or greater than 1 mg per mL are not recommended.

Infusions may be administered over a 1- to 4-hour period. Avoid rapid administration.

Do not administer intramuscularly or subcutaneously.

MINOCYCLINE

Summary of Differences

Precautions:

Laboratory value alterations—No increase in BUN concentrations.

Medical considerations/contraindications—Caution not needed in renal impairment.

Side/adverse effects: May also cause dizziness, lightheadedness, or unsteadiness (central nervous system [CNS] toxicity); and pigmentation of skin and mucous membranes.

General dosing information:

No dosage reduction in renal impairment.

May be taken with food or milk.

Additional Dosing Information

For oral dosage forms only:

- Minocycline may be taken with food or milk if gastrointestinal irritation occurs.

Oral Dosage Forms

MINOCYCLINE HYDROCHLORIDE CAPSULES USP

Usual adult and adolescent dose: Antibacterial (systemic); antiprotozoal—Oral, 200 mg (base) initially, then 100 mg every twelve hours; or 100 to 200 mg initially, then 50 mg every six hours.

Note: Gonorrhea—Oral, 100 mg (base) every twelve hours for at least four days.

Mycobacterium marinum infections—Oral, 100 mg (base) every twelve hours for six to eight weeks.

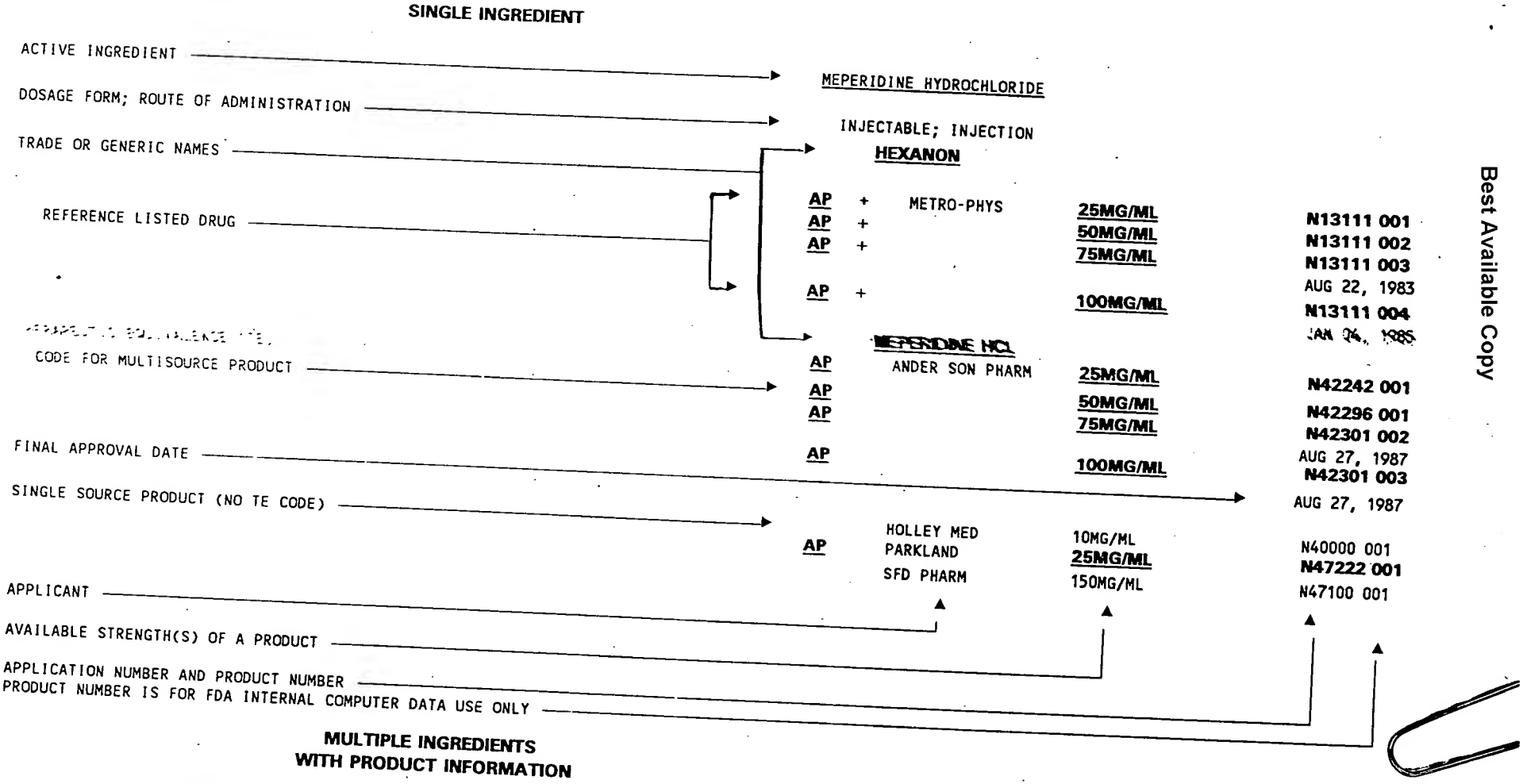
Neisseria meningitidis carriers (asymptomatic)—Oral, 100 mg (base) every twelve hours for five days.

Uncomplicated urethral, endocervical, or rectal infection caused by *Chlamydia trachomatis*—Oral, 100 mg (base) two times a day for at least seven days.

Usual adult prescribing limits: Up to 350 mg (base) the first day; then up to 200 mg a day.

Usual pediatric dose: Antibacterial (systemic); antiprotozoal—Children 8 years of age and over: Oral, 4 mg (base) per kg of body weight initially, then 2 mg per kg of body weight every twelve hours.

2.2 DRUG PRODUCT ILLUSTRATION



DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

		ADRIAMYCIN PFS			
AP	+	PHARMACIA AND UPJOHN	200MG/100ML	N50629 002	MAY 03, 1988
AP			2MG/ML	N63165 001	JAN 30, 1991
AP			200MG/100ML	N63165 002	JAN 30, 1991
		ADRIAMYCIN RDF			
AP	+	PHARMACIA AND UPJOHN	10MG/VIAL	N50467 001	
AP	+		20MG/VIAL	N50467 003	MAY 20, 1985
AP	+		50MG/VIAL	N50467 002	
	+		150MG/VIAL	N50467 004	JUL 22, 1987
		DOXORUBICIN HCL			
AP		BEDFORD	2MG/ML	N62975 001	MAR 17, 1989
AP			200MG/100ML	N64097 001	SEP 13, 1994
AP			10MG/VIAL	N62921 001	MAR 17, 1989
AP			20MG/VIAL	N62921 002	MAR 17, 1989
AP			50MG/VIAL	N62921 003	MAR 17, 1989
AP		FUJISAWA	2MG/ML	N63277 001	OCT 26, 1995
AP		GENSIA	2MG/ML	N64140 001	JUL 28, 1995
AP			200MG/100ML	N64140 002	JUL 28, 1995
AP		PHARMACHEMIE	2MG/ML	N63336 001	FEB 28, 1995
AP			200MG/100ML	N63336 004	FEB 28, 1995
AP			10MG/VIAL	N63097 001	MAY 21, 1990
AP			20MG/VIAL	N63097 002	MAY 21, 1990
AP			50MG/VIAL	N63097 003	MAY 21, 1990
		RUBEX			
AP		BRISTOL MYERS	10MG/VIAL	N62926 001	APR 13, 1989
AP			50MG/VIAL	N62926 002	APR 13, 1989

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

		RUBEX			
		BRISTOL MYERS	100MG/VIAL	N62926 003	APR 13, 1989

INJECTABLE, LIPOSOMAL; INJECTION

		DOXIL			
	+	SEQUUS	2MG/ML	N50718 001	NOV 17, 1995

DOXYCYCLINE

CAPSULE; ORAL

		MONODOX			
		OCLASSEN	EQ 50MG BASE	N50641 002	FEB 10, 1992
	+		EQ 100MG BASE	N50641 001	DEC 29, 1989

POWDER FOR RECONSTITUTION; ORAL

		DOXYCHEL			
AB		RACHELLE	EQ 25MG BASE/5ML	N61720 001	
		VIBRAMYCIN			
AB	+	PFIZER	EQ 25MG BASE/5ML	N50006 001	

DOXYCYCLINE CALCIUM

SUSPENSION; ORAL

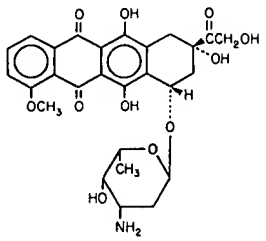
		VIBRAMYCIN			
	+	PFIZER	EQ 50MG BASE/5ML	N50480 001	

DOXYCYCLINE HYCLATE

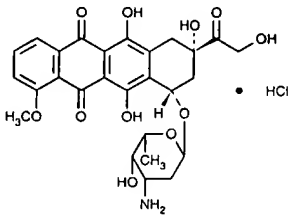
CAPSULE; ORAL

		DOXY-LEMMON			
AB		TEVA	EQ 50MG BASE	N62497 001	AUG 23, 1984
AB			EQ 100MG BASE	N62497 002	JUN 15, 1984
		DOXYCHEL HYCLATE			
AB		RACHELLE	EQ 50MG BASE	N61717 001	
AB			EQ 100MG BASE	N61717 002	
		DOXYCYCLINE HYCLATE			
AB		BARR	EQ 50MG BASE	N62418 001	JAN 28, 1983

BAN. *Antineoplastic.* Adriblastina (Farmitalia, Societa Farmaceutici Italia, Italy)

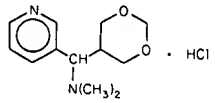


Doxorubicin Hydrochloride. USP. $C_{27}H_{29}NO_{11}.HCl$. 579.99. (1) 5,12-Naphthacenedione, 10-[(3-amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-8-(hydroxylacetyl)-1-methoxy-, hydrochloride (8*S*-*cis*)-; (2) (8*S*,10*S*)-10-[(3-Amino-2,3,6-trideoxy-α-L-*lyxo*-hexopyranosyl)oxy]-8-glycoloyl-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-5,12-naphthacenedione hydrochloride. *CAS-25316-40-9; CAS-23214-92-8* [doxorubicin]. JAN. *Antineoplastic.* Adriamycin (Pharmacia & Upjohn); (Astra); Rubex (Bristol-Myers Oncology) ✧*NSC-123127*



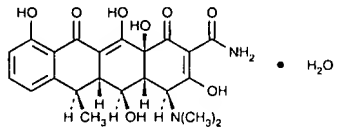
Doxpicodin Hydrochloride (previously used name) — *See* Doxpicomine Hydrochloride.

Doxpicomine Hydrochloride [*1980*] (dox pi′ koe meen). $C_{12}H_{18}N_2O_2.HCl$. 258.75. [Doxpicomine is INN.] (1) 3-Pyridinemethanamine, α-1,3-dioxan-5-yl-*N*,*N*-dimethyl-, monohydrochloride, (−)-; (2) (−)-3-[(Dimethylamino)-*m*-dioxan-5-ylmethyl]pyridine monohydrochloride. *CAS-69494-04-8; CAS-62904-71-6* [doxpicomine]. *Analgesic.* (Lilly†) *[Name previously used: Doxpicodin Hydrochloride.]* ✧*LY 108380*



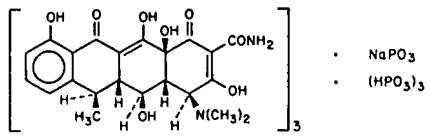
Doxybetasol (BAN) — *See* Doxibetasol.

Doxycycline [*1966*] (dox i sye′ kleen). **USP.** $C_{22}H_{24}N_2O_8.H_2O$. 462.46. [Doxycycline Hydrochloride is JAN.] (1) 2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, [4*S*-(4α,4aα,5α,5aα,6α,12aα)]-, monohydrate; (2) 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrate. *CAS-17086-28-1; CAS-564-25-0* [anhydrous]. INN; BAN. *Antibacterial.* Monodox (Oclassen); Vibramycin (Pfizer) ✧*GS-3065*



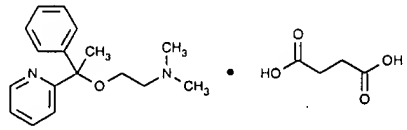
Doxycycline Calcium. USP [Oral Suspension]. *Antibacterial; antiprotozoal.*

Doxycycline Fosfatex [*1987*]. $(C_{22}H_{24}N_2O_8)_3.NaPO_3.(HPO_3)_3$. 1675.23. (1) 2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, [4*S*-(4α,4aα,5α,5aα,6α,-12aα)]-, compound with metaphosphoric acid ($H_4P_4O_{12}$) monosodium salt (3:1); (2) (4*S*,4a*R*,5*S*,5a*R*,6*R*,12a*S*)-4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,-12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide, compound with sodium trihydrogen metaphosphate ($H_3NaP_4O_{12}$) (3:1). *CAS-83038-87-3.* BAN. *Antibacterial.* (Hovione, LDA, Portugal) ✧*AB08; DMSC*



Doxycycline Hyclate. USP. $(C_{22}H_{24}N_2O_8.HCl)_2.C_2H_6O.H_2O$. 1025.89. (1) 2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, monohydrochloride, compd. with ethanol (2:1), monohydrate, [4*S*-(4α,4aα,5α,5aα,6α,-12aα)]-; (2) 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride, compound with ethyl alcohol (2:1), monohydrate. *CAS-24390-14-5; CAS-564-25-0* [doxycycline]. *Antibacterial.* (Apothecon); Doryx (Parke-Davis); (Elkins-Sinn); (Lemmon†); Vibra-Tabs (Pfizer); Vivox (Bristol-Myers Squibb†)

Doxylamine Succinate (dox il′ a meen). **USP.** $C_{17}H_{22}N_2O.C_4H_6O_4$. 388.47. [Doxylamine is INN and BAN.] (1) Ethanamine, *N*,*N*-dimethyl-2-[1-phenyl-1-(2-pyridinyl)ethoxy]-, butanedioate (1:1); (2) 2-[α[2-(Dimethylamino)ethoxy]-α-methylbenzyl]pyridine succinate (1:1). *CAS-562-10-7; CAS-469-21-6* [doxylamine]. *Antihistaminic.* Decapryn Succinate (Marion Merrell Dow†); Unisom (Pfizer); component of Robitussin Night Time Cold Formula (Whitehall-Robins)



D-Panthenol 50. BASF brand of Dexpanthenol.

DPE. Code designation for Dipivefrin.

DPN. Code designation for Nadide.

DR-3355. Code designation for Levofloxacin.

Dr. Scholl's Athlete's Foot Spray. Schering-Plough HealthCare brand of Tolnaftate.

Dr. Scholl's Callus Removers. Schering-Plough HealthCare brand of Salicylic Acid.

Dr. Scholl's Corn Removers. Schering-Plough HealthCare brand of Salicylic Acid.

Dr. Scholl's Wart Remover Kit. Schering-Plough HealthCare brand of Salicylic Acid.

Draflazine [*1993*] (dra′ fla zeen). $C_{30}H_{33}Cl_2F_2N_5O_2$. 604.53. (1) 1-Piperazineacetamide, 2-(aminocarbonyl)-*N*-(4-amino-2,6-dichlorophenyl)-4-[5,5-bis(4-fluorophenyl)pentyl]-, (±)-; (2) (±)-4′-Amino-4-[5,5-bis(*p*-fluorophenyl)pentyl]-2-carbamoyl-2′,6′-dichloro-1-piperazineacetanilide. *CAS-*

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

	DOXYCYCLINE HYCLATE			
AB	BARR	EQ 100MG BASE	N62418 002	JAN 28, 1983
AB	CHELSEA LABS	EQ 50MG BASE	N62142 001	
AB		EQ 100MG BASE	N62142 002	
AB	DANBURY PHARMA	EQ 50MG BASE	N62031 002	OCT 13, 1982
AB		EQ 100MG BASE	N62031 001	
AB	MUTUAL PHARM	EQ 50MG BASE	N62675 001	JUL 10, 1986
AB		EQ 100MG BASE	N62676 001	JUL 10, 1986
AB	MYLAN	EQ 50MG BASE	N62337 001	MAR 29, 1982
AB		EQ 100MG BASE	N62337 002	MAR 29, 1982
AB	WEST WARD	EQ 50MG BASE	N62396 002	NOV 07, 1984
AB		EQ 100MG BASE	N62396 001	MAY 07, 1984
AB	ZENITH LABS	EQ 50MG BASE	N62500 001	SEP 11, 1984
AB		EQ 100MG BASE	N62500 002	SEP 11, 1984
	VIBRAMYCIN			
AB	PFIZER	EQ 50MG BASE	N50007 001	
AB	+	EQ 100MG BASE	N50007 002	

CAPSULE, COATED PELLETS; ORAL

	DORYX			
AB	+ FAULDING	EQ 100MG BASE	N50582 001	JUL 22, 1985
AB	WARNER CHILCOTT	EQ 100MG BASE	N62653 001	OCT 30, 1985
	DOXYCYCLINE HYCLATE			
AB	SIDMAK LABS NJ	EQ 100MG BASE	N63187 001	JUN 30, 1992

INJECTABLE; INJECTION

	DOXY 100			
AP	FUJISAWA	EQ 100MG BASE/VIAL	N62475 001	DEC 09, 1983
	DOXY 200			
AP	FUJISAWA	EQ 200MG BASE/VIAL	N62475 002	DEC 09, 1983
	DOXYCHEL HYCLATE			
AP	RACHELLE	EQ 100MG BASE/VIAL	N61953 001	

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

	DOXYCYCLINE			
AP	BEDFORD	EQ 100MG BASE/VIAL	N62569 001	MAR 09, 1988
AP		EQ 200MG BASE/VIAL	N62569 002	MAR 09, 1988
AP	ELKINS SINN	EQ 100MG BASE/VIAL	N62450 001	OCT 27, 1983
AP		EQ 200MG BASE/VIAL	N62450 002	OCT 27, 1983
	DOXYCYCLINE HYCLATE			
AP	LEDERLE	EQ 100MG BASE/VIAL	N62992 001	FEB 16, 1989
AP		EQ 200MG BASE/VIAL	N62992 002	FEB 16, 1989
	VIBRAMYCIN			
AP	+ PFIZER	EQ 100MG BASE/VIAL	N50442 002	
AP	+	EQ 200MG BASE/VIAL	N50442 001	

TABLET; ORAL

	DOXY-LEMMON			
AB	TEVA	EQ 100MG BASE	N62581 001	MAR 15, 1985
	DOXY-TABS			
AB	RACHELLE	EQ 100MG BASE	N62269 001	
AB		EQ 100MG BASE	N62269 002	NOV 08, 1982
	DOXYCYCLINE HYCLATE			
AB	BARR	EQ 100MG BASE	N62391 001	SEP 30, 1982
AB	DANBURY PHARMA	EQ 100MG BASE	N62421 001	FEB 02, 1983
AB	MUTUAL PHARM	EQ 100MG BASE	N62677 001	JUL 10, 1986
AB	MYLAN	EQ 100MG BASE	N62432 001	FEB 15, 1983
AB	VINTAGE PHARMS	EQ 100MG BASE	N62538 001	APR 07, 1986
AB	ZENITH LABS	EQ 100MG BASE	N62505 001	SEP 11, 1984
	VIBRA-TABS			
AB	+ PFIZER	EQ 100MG BASE	N50533 001	